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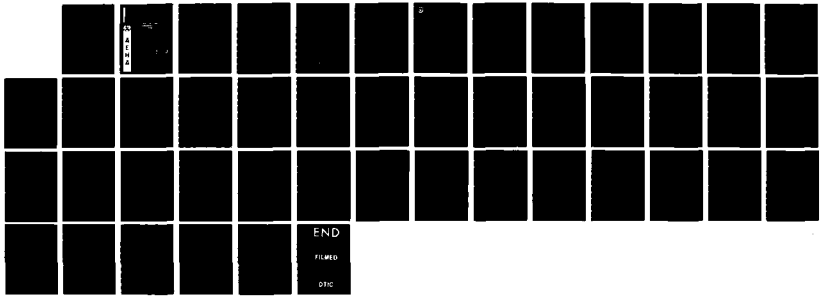

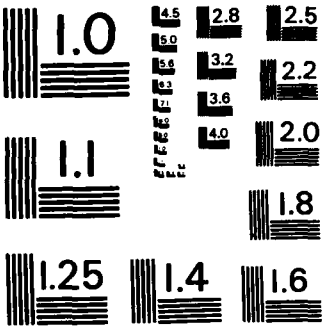

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UNITED STATES ARMY ENVIRONMENTAL HYGIENE AGENCY

ABERDEEN PROVING GROUND, MD 21010-5422

EVALUATION AND CONTROL OF OCCUPATIONAL EXPOSURE TO ETHYLENE OXIDE IN HEALTH CARE FACILITIES

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This publication provides guidance to preventive medicine personnel for use in evaluating and controlling occupational exposure to ethylene oxide in US Army health care facilities. Specific topics include exposure monitoring, engineering control measures, work practices and administrative controls, sampling methods and ventilation guidelines.

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APPENDIXES

DEPARTMENT OF THE ARMY
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REPLY TO
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EVALUATION AND CONTROL OF OCCUPATIONAL EXPOSURE TO ETHYLENE OXIDE IN HEALTH CARE FACILITIES

CHAPTER 1

GENERAL

1-1. PURPOSE. This publication provides guidance to preventive medicine personnel for use in evaluating and controlling occupational exposure to ethylene oxide (ETO) in US Army health care facilities.

1-2. REFERENCES. References are listed in Appendix A.

1-3. INTRODUCTION.

a. The continued use of ETO as a gaseous sterilant in hospitals is essential if the full benefits of modern medical technology are to be enjoyed. Techniques such as corneal and organ transplants, cardiac catheterization, and prosthesis implantation would be extremely difficult, if not impossible, to perform without ETO sterilization of associated supplies and instrumentation.

b. Exposure of hospital employees to ETO can occur during routine sterilization operations, and when maintenance is performed on the ETO sterilizer. Of particular concern are the reported carcinogenic, mutagenic and teratogenic effects of ETO exposure. To protect the health of hospital workers, the extent of ETO exposure must be characterized. The ETO concentrations in ambient air can be measured by a variety of sampling methods. Once the extent of exposure is known, engineering or administrative control measures can be implemented to reduce employee's exposure.

Use of trademarked names does not imply endorsement by the US Army, but is intended only to assist in identification of a specific product.

1-4. BACKGROUND.

a. The Occupational Safety and Health Administration (OSHA) prescribed the frequency of environmental monitoring for ETO in its final rule issued in June 1984. The final rule lowers the permissible exposure limit (PEL) from a 50 parts per million (ppm) time-weighted average (TWA) concentration to a 1 ppm TWA concentration with a 0.5 ppm action level. As a direct consequence, many hospitals that previously were not required to monitor ETO exposure because ambient concentrations were under the then current PEL are now faced with the prospect of periodically measuring the levels of ETO to which employees are exposed. Highlights of significant changes from the new OSHA standard (29 CFR 1910.1047, Ethylene Oxide) are in Appendix B.

b. In addition to measuring the levels of ETO in the work environment, the following factors must be examined to thoroughly characterize potential exposures:

(1) Existing engineering controls such as general and local exhaust ventilation (LEV).

(2) Existing administrative controls such as limited access areas and time of sterilizer operation.

(3) Existing work practices.

(4) Available personal protective equipment.

1-5. EXPOSURE MONITORING.

a. The OSHA standard (1910.1047(d)(2)) requires initial workplace monitoring to accurately determine the airborne concentration of ETO to which employees are exposed. Although the OSHA standard does not require area monitoring, such monitoring is useful in characterizing potential exposures. The initial monitoring procedure should consist of:

(1) *Environmental (general area) monitoring* of the:

(a) ETO sterilizer work area.

(b) Mechanical/equipment room or maintenance access area behind the sterilizer(s).

(c) Aerator area.

(d) Work areas adjacent to the central materiel supply (CMS).

(2) *Personnel (breathing zone) monitoring* of:

(a) CMS personnel.

(b) Personnel in work areas adjacent to the CMS if potential exposures are indicated by environmental monitoring in those areas.

(3) *Equipment leak testing* during use of:

(a) *Sterilizers*, to include:

- Door gaskets.
- Valves and gauges.
- Plumbing connectors on sterilizer.
- ETO gas line.
- Drain and associated plumbing.
- Ventilation ductwork (LEV).

(b) *Aerators*, to include:

- Door gaskets.
- Ventilation ductwork (LEV).

(c) *ETO tanks*, to include:

- Valves and gauges.
- ETO gas line
- Tank change-over procedures.

b. Judgment is required in order to obtain a representative sample, since ETO exposure levels are not constant throughout the workshift. The ETO levels change rapidly during a sterilization cycle; they typically peak during the chamber exhaust and air flush and when the door is opened at the end of the cycle. Although OSHA has decided not to issue a short-term exposure limit (STEL) for ETO, personnel breathing zone samples should be obtained during these relatively short periods of peak concentration to further define the extent of exposure and adequacy of existing control measures. A real-time direct reading analytical instrument can aid in determining when appropriate short-term samples should be obtained from the breathing zones of exposed personnel.

CHAPTER 2

EXPOSURE MONITORING

2-1. SAMPLING METHODS.

a. Methods available for sampling ETO are based on the principles of photoionization, gas chromatography, infrared absorption spectrophotometry, active and passive adsorption on a collecting medium with subsequent chromatographic analysis, and active and passive absorption in a liquid medium with subsequent colorimetric analysis. Collection on charcoal tubes and analysis by gas chromatography has proven to be an effective way of monitoring ETO exposure if appropriate precautions are followed. The portable infrared analyzer can specifically identify and quantify low levels of ETO, and when coupled with a strip chart recorder, a TWA concentration may be computed. Passive diffusional samplers are available for measuring the TWA exposure to ETO. The US Army Environmental Hygiene Agency (USAEHA) has developed and validated an active (tube and pump) sampling method that eliminates most of the problems encountered during the charcoal tube active sampling procedure.

b. Real-time, direct reading instruments can yield a time-concentration profile of ETO exposure. They are also useful in detecting areas of high localized concentrations and sources of leaks in equipment, which should result in corrective actions that reduce overall worker exposure. Examples of this type of instrument are the:

(1) MIRAN® IA, IB, and 103 infrared spectrophotometers (see Appendix C).

(2) HNU PI101 photoionization detectors.

(3) Catalyst Research electrochemical analyzer.

(4) Century OVA® 128.

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c. Active (tube and pump) sampling methods are effective for determining TWA concentrations for general area (environmental) and personnel breathing zone samples. Passive diffusional samplers are best suited for determining an employee's breathing zone exposure concentration. The following sampling methods are described in Appendix C.

(1) National Institute for Occupational Safety and Health (NIOSH) PCAM method S-286, a charcoal tube method.

(2) Qazi-Ketcham charcoal tube method (SKC catalog No. ST 226-36).

(3) OSHA method number 30, a charcoal tube method.

(4) Supelco ORBO®-78 ethylene oxide tube method.

(5) 3M® 3550 and 3551 passive diffusional samplers.

2-2. SAMPLING STRATEGY.

a. Sampling Frequency. Personnel breathing zone sampling will be conducted during sterilization and aeration to determine ETO exposure levels. Since a wide range of potential exposures is expected, all employees in the CMS area should be initially sampled. If a large number of employees work during the same shift, a sampling scheme should be devised, with the number of individuals sampled based on the total number of employees to reflect a 95 percent confidence level ($p = 0.05$) that the highest and lowest exposed individuals will be included in the sampling. For practical purposes, this means that for groups of 11 or fewer employees on each shift, all must be sampled. Table A-2 of NIOSH publication 77-173, Occupational Exposure Sampling Strategy Manual, should be consulted when there are 12 or more workers on the same shift. Ancillary jobs in the CMS area or jobs in areas adjacent to the CMS, in which exposure to ETO is intermittent or thought to be nonexistent, will also be evaluated to the extent possible through general area samples. This sampling data on

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background exposures can be used as a baseline to which CMS employee exposure could be compared. Breathing zone sampling of CMS employees will be conducted quarterly if exposure is above the 1 ppm PEL, and semiannually if exposure is between 0.5 ppm and 1 ppm. Although not required by OSHA, it is the Office of The Surgeon General's (OTSG) policy to sample at least annually if the exposure is below the 0.5 ppm action level.

b. Sampling Techniques. A brief purpose of the various sampling techniques is given in table 2-1 and explained in detail in paragraphs c through e below.

TABLE 2-1
Purpose of Sampling Techniques

Sample Type	Purpose
Personnel breathing zone sample	To determine 8-hour TWA exposures to ETO by job type. To determine peak exposure levels, short-term breathing zone samples will also be collected from any individual(s) transferring the load to the aerator.
General area sample	To characterize airborne (ambient or background) concentrations of ETO by work area.
Real-time monitoring	To characterize intraday concentration variations of ETO by area within the CMS.

c. Breathing Zone Sampling.

(1) Personnel breathing zone sampling can be conducted by attaching a sampling pump and collection media to an individual employee or by using a passive diffusional sampler on the employee. The sampling device will be placed on the lapel of the employee to sample breathing zone concentrations. All sampling will be conducted according to the procedures contained in Appendix C.

(2) The purpose of personnel sampling is to determine how the employee's TWA exposure compares with the OSHA 8-hour PEL of 1 ppm. The following factors affect the employee's exposure and should be documented during sampling.

(a) The amount of ETO available for release at the source can be determined from the sterilizer and load variables; however, this is an academic exercise that is not germane to measuring actual employee exposure.

(b) The events which take place during the sampling period.

(c) The activities of workers being sampled.

(d) The time spent in various areas of high or low ETO concentration should be noted.

(e) Work practices which may affect the potential for exposure should be noted.

(f) Performance of existing engineering control measures.

(3) The number of employees in the CMS will depend on the size of the hospital. It is not uncommon to assign one employee the duty of loading and unloading all the sterilizers, both steam and ETO, for varying periods of time. The duty is assigned on a rotating basis, and often is performed at night. Other CMS jobs involve preparing and packaging the items to be sterilized and decontaminating items returning from use in the hospital. As a minimum, the sterilizer operator and one or two workers who prepare and package items for sterilization should be sampled. Two consecutive partial-period samples should be taken, in duplicate if resources permit, using one of the methods in Appendix C. Each sample will be collected for approximately 4 hours at a flow rate of 30 mL/min. (The lunch break is a good time to switch sample tubes.) Duplicate samples should be placed as closely together on the person (same lapel) and as near the breathing zone as possible. Duplicate short-term samples should also be obtained from the breathing zone of the sterilizer operator at the end of the cycle (when the sterilizer door is opened, and during load transfer to the aerator). Each sample will be taken using a sampling rate of at least 100 mL/min for approximately 20 minutes.

(4) This sampling strategy may require modifications to account for differences in each hospital's CMS and sterilization procedures. For example, beginning a sterilization cycle during one shift and unloading the sterilizer during another shift would necessitate at least one more period of sampling.

d. General Area Sampling.

(1) General area sampling will indicate if the ETO concentration in the air at a point representing a selected work area differs significantly from the concentration at the sterilizer. The events which take place during each sampling period and the location of the sampling sites must be documented. Air movement should be observed to determine if the sampling sites are in the zone of effect of a ventilation hood or strong room air current. Work practices which may have a significant effect on the ambient levels of ETO, such as the way the sterilizer door is opened and the length of time it is open, should be noted.

(2) Duplicate samples should be collected from three to five locations using an appropriate active sampling method with a minimum sampling rate of 30 mL/min. A full 8-hour shift may require two 4-hour samples which should coincide with the periods for personnel breathing zone sampling. Area samples will consist of one or two source (sterilizer) samples, one or two ambient workroom air samples, and a background area sample. Source samples will be as close to the breathing zone in front of the sterilizer door as possible without interfering with the operator's access to the sterilizer. The location of the sampling device will approximate worst case employee exposure. The ambient workroom samples will be at breathing-zone height near a sampled worker's workstation, such as a wrapping table.

e. Real-Time Monitoring.

(1) Although the PEL is stated as an 8-hour TWA, the exposure profile for a typical sterilizer operator is seldom a constant value for the duration of the workshift. Sterilizer operators can routinely be exposed to very high breathing zone concentrations for very brief periods while transferring freshly sterilized goods to the aerator. The data reported in the literature suggests that brief, peak exposures up to 1000 ppm for 2 minutes are possible. Such exposure profiles are not easily measured with long-term integrated sampling methods. Consequently, a monitoring technique capable of assessing the instantaneous exposure concentrations should be used.

(2) Infrared spectrophotometers, such as Foxboro MIRAN infrared analyzers (models IA, IB, and 103), are real-time monitors that can be used to complement the TWA sampling strategy. Appendix C describes the use of MIRAN spectrophotometers, as does USAEHA Technical Guide 031.

CHAPTER 3

ENGINEERING CONTROL MEASURES

3-1. EVALUATION OF VENTILATION SYSTEMS.

a. General. In order to evaluate the overall effectiveness of the CMS control measures, the components of the ventilation system, both LEV and general dilution ventilation must be adequately characterized. Each component plays a role in controlling the exposure to ETO. The basic question is: How much does the ventilation system contribute to the control of the employee's ETO exposure? To answer this question, the pertinent variables should be measured. Factors related to the overall effectiveness of the ventilation system include:

(1) The total exhaust volumetric flow rate with respect to room size.

(2) The ratio of makeup air to total exhaust volumetric flow rate.

(3) The concentration of ETO in the supply air.

b. Measurement of Ventilation Factors.

(1) The total volumetric flow rate exhausted from the room is the sum of the individual local exhaust and general ventilation exhaust flow rates. This quantity should be compared with the corresponding value for the total flow rate of air supplied to the room. A positive differential air pressure with respect to areas outside the clean area of the CMS must be maintained so that air which may contain infectious agents does not enter the sterile supply room. To ensure positive differential air pressure, there should be at least a 10 percent excess of supply air. This excess will also assure that the ventilation systems are working at peak capacity, since they will not have to draw against a negative pressure. The differential pressure condition between the CMS and the surrounding areas can be checked using a smoke tube at the doorways to show if air is being pushed out of the CMS, indicating the desired positive pressure, or drawn into the CMS, indicating a net negative pressure. If the ETO sterilizer is located in a separate room, the room should be under negative differential pressure with respect to the rest of the CMS. If the sterilizer is flush-mounted into a wall, the mechanical access area behind the wall should likewise be under negative air pressure. The negative pressure will help prevent the spread of ETO to other CMS areas.

(2) The air coming from the supply air inlets can be sampled briefly with a direct reading instrument at various times during the survey to determine if there is a measurable concentration of ETO in the air returned to the room. There must be no recirculation, intentional or otherwise, of ETO contaminated air previously exhausted from the room.

(3) Ventilation system volumetric flow rates are best determined by multiplying the average duct velocity by the cross-sectional area at a convenient point of measurement. Ventilation duct air velocities can be measured by Pitot traverse as described in the current edition of the American Conference of Governmental Industrial Hygienists (ACGIH) Industrial Ventilation Manual. Since the sterilization operation emits warm, moist air, a density correction may be required to account for temperature and moisture deviations from standard conditions when measuring air velocity. This is especially true if one or more steam sterilizers are in the same location as the ETO sterilizer.

(4) If access to the exhaust and supply ducts is restricted, the total room air flow can be estimated by measuring the average velocity readings at each duct opening. These velocity measurements can be taken using a hot-wire anemometer, which is particularly useful for an air flow range of 10 to 2000 ft/min. The instrument should not be used in air temperatures greater than 150 °F (65.6 °C). The volumetric air flow rate through the local exhaust system can be estimated by multiplying the average face velocity measurement by the cross sectional area of the duct opening. Face velocity measurements are also useful for apportioning a total exhaust air flow between two or more branches General air flow rates can be computed for each branch and summed to obtain the total volumetric flow rate.

(5) Air flow patterns can be observed by using standard smoke tubes. These tubes emit a thin trail of a chemical smoke when air is passed through them. The direction and the speed of air movement estimated by visualizing these patterns provides information on the potential exposure of employees while working in an airflow path between an exposure source and the exhaust.

(6) The data characterizing the ventilation systems should be compared to the recommendations found in the literature and presented here and in Appendix C. Face velocities at the hood over a sterilizer should be 100 cfm per square foot of sterilizer door area. The airflow patterns around the sterilizer door visualized through use of smoke tubes can provide an indication of the efficiency of the hood and its capture velocity.

3-2. LOCAL EXHAUST VENTILATION.

a. General. Local exhaust ventilation is important in limiting the amount of ETO which leaves the airspace immediately in front of the sterilizer door opening, as well as other areas such as around the drain, the pressure relief valve, and above the supply cylinders. Certain factors determine the effectiveness of a LEV system such as:

(1) Dimensions of the LEV hood(s) and source(s) to be controlled.

(2) Hood design and location (i.e., above, below, or along side of source(s) to be controlled).

(3) Air flow patterns between the hood and around the source(s) to be controlled.

(4) Hood flow rate.

(5) Hood face velocity.

(6) Capture velocity around the source(s) to be controlled.

(7) Ambient air velocity around source(s) to be controlled.

(8) System design specifications.

b. Evaluating the LEV. In evaluating the LEV system several measurements and observations are necessary. First, the exhaust hood should be characterized by its shape, dimensions, and location with respect to the exposure source (sterilizer door or drain). Second, air flow patterns around and between possible ETO release points and the ventilation hood(s) can be observed using smoke tubes as described above. Third, the volumetric flow rate for the system and each branch duct should be determined; measurements can be made of the hood face velocity, capture velocity, selected airflow velocities between the source and the hood, and the ambient air velocities around the source. Finally, the system design specifications can be checked. Sterilizer ventilation guidelines are contained in Appendix D.

3-3. GENERAL DILUTION VENTILATION.

a. General. The proper use of general dilution ventilation can effectively reduce the ambient concentration resulting from ETO sources not controlled by other measures. The variables affecting the efficacy of general dilution ventilation as a control measure are:

(1) The size and layout of the department.

(2) The location of supply air inlets and exhaust outlets.

(3) The air flow rate at each inlet and outlet.

(4) Air flow patterns within room.

(5) System design specifications.

b. Evaluating General Ventilation. One measure of general ventilation performance is the ratio of the total volumetric flow rate exhausted from the room relative to the room volume. The Army design criteria contained in TM 5-838-2, Army Health Facility Design, is 10 air changes per hour, which means a quantity of air equal to or greater than 10 times the room volume should be exhausted each hour. In assessing the general ventilation, a floor plan should first be obtained or drawn and the pertinent dimensions of the ETO sterilization area measured, noting the location of the supply air inlets and exhaust air outlets. The volumetric flow rates and grill face velocities for each should be measured, and the airflow between and around the possible ETO release points, workstations, ventilation openings, and other selected points in the room observed using smoke tubes. Where possible, information on the system design, including duct sizing, fan ratings, and the provision for makeup air or recirculation, should be obtained from engineering drawings or inspection. Finally, results should be compared to the system design specifications in order to determine if the system is functioning as designed.

CHAPTER 4

WORK PRACTICES AND ADMINISTRATIVE CONTROLS

4-1. WORK PRACTICES.

a. Observations of the employee's work practices are a very important part of characterizing an individual's exposure to ETO. For a given situation with a certain potential exposure and a particular combination of control measures, the actual employee exposure can vary considerably depending solely on how the worker does the job. The following variables can be evaluated by observation:

(1) The job tasks of each worker to be sampled.

(2) The workstation for each task.

(3) The time spent at each task.

(4) Identification of high exposure tasks.

(5) The door opening procedure at the end of the cycle.

(6) The method of removing items from sterilizer - individually or in a basket.

(7) Time and path for transferring items from the sterilizer to the aerator.

(8) Handling of a transfer cart (if used) (i.e. is it pulled or pushed to aerator?).

(9) The amount of handling of sterilized items, to include policy on removing the biological indicator for quality assurance.

(10) Access to the aerator during the aeration cycle.

(11) Use of personal protective equipment.

b. The job tasks of each worker should be listed, along with the workstations where they are performed and the average time spent on each task during the workday. From this list, potentially high exposure tasks can be identified. Certain tasks, such as opening the sterilizer door and handling the sterilized items, should be watched to determine if the manner with which each is done contributes to an increased potential for exposure to or the emission of ETO. The use of personal protective equipment should be noted. These observations can be used to interpret the sample results obtained from the survey.

c. For an excellent review of good ETO work practices, refer to Ethylene Oxide Use in Hospitals, A Manual for Health Care Personnel, by the American Society for Hospital Central Service Personnel of the American Hospital Association.

4-2. ADMINISTRATIVE CONTROLS.

a. The CMS supervisor must develop and enforce written SOPs for each major task to be performed by employees. Particular attention should be given to the potentially high exposure tasks identified above.

b. Demarcation of areas that exceed the PEL for ETO, such as areas with an 8-hour TWA ETO concentration greater than 1 ppm, and limiting access to these areas will significantly reduce incidental employee exposure to ETO. A simple method for identifying such restricted areas is the use of brightly colored tape on the floor at the boundary of the area. The tape serves as a visual reminder for the employee, and reinforces the content of the required warning signs [29 CFR 1910.1047(e)].

4-3. SPILL CONTROL.

a. Under proper hospital working conditions, the major health concerns with ETO result from chronic exposures to relatively small amounts of the gas. However, in the event of a major ETO spill or leak, acute personnel exposures become the primary health concern. In high concentrations, ETO irritates the skin, eyes, and respiratory tract of exposed personnel. This respiratory tract irritation may lead to a secondary infection of the lung and in some cases, eventual death.

b. In the event of a major spill, nonflammable mixtures of ETO cannot be counted on to maintain their nonflammable characteristics once they have left the container. Under the emergency conditions of a severe ETO spill or leak, swift and timely action is necessary to protect worker health and prevent possible property damage.

c. Some steps must be taken before a spill occurs. Effective planning reduces panic and confusion, and may even head off some problems before they can occur.

(1) Every facility using ETO sterilization should have a SOP for an ETO emergency spill control plan. It should provide very specific guidelines covering the entire spill scenario from prespill planning to final hazard elimination. Areas of responsibility, personnel requiring notification, and sources of support should all be included in the SOP.

(2) Carbon dioxide, alcohol foam, or dry chemical fire extinguishers should be placed in readily accessible areas near a possible spill. Personnel should be trained and drilled in the proper use of the extinguishers.

(3) Shut-off switches for motors and other spark producing devices in ETO use areas should be located and noted.

(4) The ventilation in the CMS area should be examined, and a determination made as to suitability for use in exhausting any spilled ETO. If the CMS air is recirculated to any other location in the hospital, this ventilation may have to be turned off in the event of a spill to prevent the ETO from spreading to other hospital locations.

(5) Sources of acceptable respirators and other personal protective equipment should be found. Rapid access to these items in the event of an ETO emergency should be arranged.

(a) Respirators should be full-facepiece to protect the face and eyes from the irritating effects of ETO gas. In instances where the ETO concentration is not known, the respirators must be pressure demand or positive pressure mode self-contained breathing apparatus (SCBA) or supplied air respirators. Because of the stringent OSHA training and maintenance requirements for supplied air respirators (29 CFR 1910.134), the use of these devices by CMS personnel is not recommended. Arrangements should be made to have the fire department or installation spill response team respond to major ETO spills. These individuals are trained and routinely work with SCBA. Where the ETO concentration is known to be under 50 ppm, NIOSH-approved canister type gas masks are acceptable. A copy of the ETO Spill SOP should be provided to the fire department and the installation spill response team. Input from these two activities may also be helpful in the development of the SOP.

(b) Because of ETO's great penetrating ability, care should be taken in choosing which types of gloves are used for cleanup operations. Generally, disposable rubber or latex gloves should not be used except for short periods because they will hold ETO and can cause skin burns. Heavy neoprene gloves are better for cleanup.

(6) The fire department may have access to portable ventilation fans. In an emergency, it may be necessary to use these to vent ETO to the outside. However, if the ETO concentration is in or near the flammable range (3 to 100 percent) these portable fans must not be used unless they are nonsparking or intrinsically safe.

(7) Acceptable methods for disposing of faulty or leaking ETO cylinders should be discussed with logistics and fire department personnel, the installation spill response team and the gas supplier. Routes of exit with a leaking cylinder should be planned and rehearsed.

(8) Practice drills should be conducted. These may point out problems with the ETO emergency plan that are much better discovered in a dry run than in an actual spill situation. Personnel become familiar with their responsibilities through drills.

(9) Periodic monitoring of the ETO sterilizer and support equipment should be done by qualified personnel. In addition to ensuring that chronic exposures are being kept to a minimum, this monitoring may locate leaks while they are still small.

d. In the event of an ETO spill, a number of procedures must be carried out to properly control the hazard and protect personnel and property. These procedures are given below and should be outlined in the SOP.

(1) CMS personnel exposed, or with a potential of being exposed, to the leaking ETO should be evacuated. Those who have been exposed to high ETO concentrations should be observed for possible delayed effects, including nausea, vomiting, and respiratory tract problems. Persons who contacted liquid ETO should shower immediately. If liquid ETO got into their eyes, they must be flushed immediately with copious amounts of water for at least 20 minutes. Followup medical attention must be obtained as soon as possible.

(2) The fire department should be notified immediately, and should be standing by in case a fire develops. They may also be able to provide needed equipment and manpower. In addition, environmental health and safety personnel should be called in to help direct the cleanup procedures and assess the extent of the ETO hazard. The facilities engineers should be contacted to provide information on the ventilation system. Medical maintenance may have to be brought in to repair the leak. Logistics personnel should ready their defective gas cylinder disposal plan for possible execution. The operating suites and other departments who depend on CMS for support should also be notified so that they can plan for a possible disruption of services.

(3) Only authorized personnel wearing full-facepiece respirators (NIOSH-approved canister gas masks (for concentrations under 50 ppm), SCBA, or supplied air breathing apparatus) and protective equipment should enter the ETO contaminated area. Gloves should be impervious to ETO. Rubber and latex disposable gloves should not be used except for very short periods.

(4) The sterilizing area should be sealed off after contamination to prevent further spreading of the ETO. This may simply be a matter of closing doors to slow the dispersion of the gas or may involve shutting down the ventilation system to prevent recirculation of ETO contaminated air to other hospital areas.

(5) All ignition sources, including motors and other spark producing devices, should be removed from the ETO contaminated area or shut off.

(6) Any leak in the ETO cylinder should be capped by qualified personnel. If this is not possible, then the cylinder must be taken to a safe place in the open air and the leak repaired or the gas allowed to escape. Personnel removing the cylinder, and those present while it is emptying, should wear approved ETO respirators and personal protective equipment.

(7) The contaminated air should be vented to the outside. Portable ventilation fans along with open windows and existing LEV can be used. However, care should be taken to ensure that the ETO concentration is not in or near the flammability range unless the ventilation blades are nonsparking or intrinsically safe.

(8) Liquid ETO can be wiped up with paper towels by personnel wearing proper gloves and respirators. The towels can then be placed in a lab hood, aerator, or other safe place for evaporation of the ETO from the paper before disposal.

(9) All clothes and shoes contaminated with ETO liquid or droplets should be removed at once and placed in sealed containers for eventual disposal or decontamination.

e. Further spill control information can be found in the following references:

(1) Health Industry Manufacturers Association Report 80-4, The Safe Use of Ethylene Oxide.

(2) NIOSH Publication No. 77-200, Special Occupational Hazard Review with Control Recommendations - Use of Ethylene Oxide as a Sterilant in Medical Facilities.

(3) NIOSH Publication No. 78-210, Pocket Guide to Chemical Hazards.

CHAPTER 5

INFORMATION AND TRAINING

5-1. GENERAL.

a. The final ETO standard (29 CFR 1910.1047) requires employers to provide a training program for all employees expected to be exposed to airborne ETO at or above the action level of 0.5 ppm. The training requirement in the standard is patterned after OSHA's Hazard Communication standard [29 CFR 1910.1200(h)(1) and (2)].

b. Training and information requirements are routine components of OSHA health standards. Informed employees are essential to the operation of any effective occupational health program. The Army believes that informing and training employees about the chemical hazards to which they are exposed will contribute substantially to reducing the incidence of occupational diseases.

5-2. SCOPE OF TRAINING. The employer will provide employees who are potentially exposed to ETO at or above the action level with information and training on ETO at the time of initial assignment and at least annually thereafter [29 CFR 1910.1047(j)(3)].

a. Employees will be informed of the following:

(1) The requirements of 29 CFR 1910.1047(j) with an explanation of its contents including appendices A and B of the final standard.

(2) Any operations in their work area where ETO is present.

(3) The location and availability of the written ETO final rule.

(4) The medical surveillance program required by 29 CFR 1910.1047(i) with an explanation of the information in appendix C of 29 CFR 1910.1047.

b. Employee training shall include at least:

(1) Methods and observations that may be used to detect the presence or release of ETO in the work area (such as monitoring conducted by the employer, continuous monitoring devices, etc.).

(2) The physical and health hazards of ETO.

(3) The measures employees can take to protect themselves from hazards associated with ETO exposure. This includes specific procedures the employer has implemented to protect employees from exposure to ETO, such as work practices, emergency procedures, and personal protective equipment to be used.

(4) The details of the hazard communication program developed by the employer, including an explanation of the labeling system and how employees can obtain and use the appropriate hazard information.

Appendix A
References

TM 5-838-2	(Army Health Facility Design)
Title 29 CFR Section 1910.134	(Respiratory Protection)
Title 29 CFR Section 1910.1047	(Ethylene Oxide)
Title 29 CFR Section 1910.1200	(Hazard Communication)
NIOSH Publication No. 77-173	(Occupational Exposure Sampling Strategy Manual) (This publication is available from Publications Dissemination, DTS, NIOSH, 4676 Columbia Parkway, Cincinnati, OH 45226.)
NIOSH Publication No. 77-200	(Special Occupational Hazard Review with Control Recommendations - Use of Ethylene Oxide as a Sterilant in Medical Facilities) (This publication is available from Publications Dissemination, DTS, NIOSH, 4676 Columbia Parkway, Cincinnati, OH 45226.)
NIOSH Publication No. 78-210	(Pocket Guide to Chemical Hazards) (This publication is available from Publications Dissemination, DTS, NIOSH, 4676 Columbia Parkway, Cincinnati, OH 45226.)

TG No. 143	August 1985
USAEHA Technical Guide No. 031	(Use of MIRAN 103® for Measurement of Waste Anesthetic Gases and Ethylene Oxide at AMEDD Facilities) (This publication is available from Commander, US Army Environmental Hygiene Agency, ATTN: HSHB-AA, Aberdeen Proving Ground, MD 21010-5422.)
USAEHA Technical Guide No. 141	(Industrial Hygiene Sampling Instructions) (This publication is available from Commander, US Army Environmental Hygiene Agency, ATTN: HSHB-AA, Aberdeen Proving Ground, MD 21010-5422.)

Appendix B
Highlights of Significant Changes in the ETO Standard*

B-1. PERMISSIBLE EXPOSURE LIMITS [29 CFR 1910.1047(c)].

a. The PEL for occupational exposure to ETO was reduced from 50 ppm as a TWA to a 1 ppm TWA. An action level of 0.5 ppm TWA has been established; no STEL has been established. The basis for this standard is a determination by OSHA that exposure to ETO presents a carcinogenic, mutagenic, genotoxic, reproductive, neurologic, and sensitization hazard to workers.

b. Facilities with exposure levels under the action level will be exempt from complying with certain requirements of this standard (e.g., employee exposure monitoring and medical surveillance).

B-2. MONITORING FREQUENCY [29 CFR 1910.1047(d)]. Separate measurements for each employee are not required as long as the monitoring strategy is representative of all employee exposure. The employer must notify employees in writing within 15 working days after receipt of sampling results. The monitoring requirements are--

a. If initial monitoring indicates exposure levels between 0.5 ppm and 1 ppm, monitoring must be conducted semiannually. If two consecutive measurements made at least 7 days apart show exposure below 0.5 ppm, monitoring can be discontinued. However, it is OTSG policy to sample for ETO at least annually.

b. If initial monitoring indicates exposure levels above 1 ppm, monitoring must be conducted quarterly. If two consecutive measurements made at least 7 days apart show exposure below 1 ppm, the frequency can be reduced to semiannually.

c. If initial monitoring indicates exposure levels below 0.5 ppm, monitoring may be discontinued. Note that annual monitoring is still required by OTSG policy.

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*The final standard which appeared in 49 FR 25734-25808, 22 June 1984, has been codified as 29 CFR 1910.1047.

d. Additional monitoring is required if there are any changes in the production, process, or control measures that may result in new or additional exposure to ETO.

e. Monitoring must be accurate with a 95 percent confidence limit to within 25 percent for 1 ppm and within 35 percent for 0.5 ppm.

f. Employees or their representative are entitled to observe monitoring.

B-3. COMPLIANCE [29 CFR 1910.1047(e), (f), and (j)].

a. If the TWA exposure level is above 1 ppm, the employer must establish a regulated area to limit access to authorized personnel in order to minimize exposure.

(1) Signs will be posted stating:

DANGER.
ETHYLENE OXIDE.
CANCER HAZARD AND REPRODUCTIVE HAZARD.
AUTHORIZED PERSONNEL ONLY.
RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED TO BE WORN IN THIS AREA.

(2) Containers of ETO must be labeled:

CAUTION.
CONTAINS ETHYLENE OXIDE.
CANCER AND REPRODUCTIVE HAZARD.

The label must also include appropriate warnings against inhalation of or contact with ETO.

b. Engineering controls and work practices to reduce and maintain employee exposure to less than 1 ppm must be developed, implemented, and reviewed annually. A written plan must be made available to OSHA upon request. If such practices are not feasible, the employer must reduce exposure to the lowest achievable levels and supplement protection by requiring the use of respirators approved for use in atmospheres containing ETO.

B-4. MEDICAL SURVEILLANCE [29 CFR 1910.1047(i)].

a. Employers are required to institute a medical surveillance program for all employees exposed to ETO levels at or above the action level (0.5 ppm) for at least 30 days per year. The content of medical examinations will include--

(1) Comprehensive medical and work histories with special emphasis on symptoms related to eyes, blood, blood-forming organs, lungs, nervous and reproductive systems, and skin.

(2) Comprehensive physical examinations with particular emphasis on the above systems and organs.

(3) Complete blood counts to include at least a white cell count, a differential cell count, red cell count, hemoglobin, and hematocrit.

(4) If requested by employee, pregnancy test or laboratory evaluation of fertility (e.g. microscopic evaluation of a sperm sample).

(5) Any laboratory or other test which the examining physician deems necessary by sound medical practice. This includes evaluation to determine if an employee is medically unable to use personal protective equipment such as a respirator.

b. Examinations will be conducted at least annually or more often as prescribed by a physician and upon termination of employment or reassignment to a nonexposure work area. After each examination, the physician must inform the employee of the results of the examination, prepare a written opinion about the employee's risk from ETO exposure, and submit it to the employer. The employer will provide a copy of the physician's written opinion to the affected employee within 15 days from its receipt.

B-5. INFORMATION AND TRAINING [29 CFR 1910.1200(h)(2) and 29 CFR 1910.1047 (j)(ii)(iii)]. The OSHA outlines the content of training programs for employees exposed at or above the 0.5 ppm action level. This training is intended to include the hazards to which employees are exposed; the necessary steps to protect themselves from exposure (including emergencies); limitations and the proper use of respirators and other personal protective equipment; a description of medical examinations and their purpose; implementation of work practices and the use of available engineering controls; and the contents of the OSHA standard.

B-6. RECORDKEEPING [29 CFR 1910.1047(k)]. Even if exposures are below the action level, all employers must maintain records of exposure level monitoring and medical surveillance for employees and former employees. The employees or their designated representatives must have access to the records upon request. Records must be retained for the period of employment plus 30 years, and the employer must notify OSHA in writing 3 months prior to disposal of such records.

Appendix C
Sampling and Analytical Methods for ETO

Section I. Sampling Methods

C-1. INTRODUCTION.

a. Personnel breathing zone sampling must be conducted to determine the representative exposure concentrations for employees occupationally exposed to ETO. General area sampling provides valuable data that can be used to evaluate existing control measures as well as determine ETO concentrations in different CMS areas. Sampling methods can be categorized as either integrated methods which provide a TWA concentration over the duration of the sample period, or real-time methods which give an instantaneous indication of concentration. Real-time methods can also be used to get an integrated TWA concentration.

b. Integrated sampling methods can be either an active method which draws air through a sorbent by mechanical means, or a passive method, which relies on diffusion of the contaminant to the sorbent medium. Several of the more common active and passive sampling methods are described in the following paragraphs, as are the direct-reading MIRAN infrared spectrophotometers.

C-2. ACTIVE (TUBE AND PUMP) SAMPLING METHODS.

a. The NIOSH S-286 (1976) sampling method for ETO was not validated below 20 ppm; therefore, alternative sampling methods have been developed. NIOSH is evaluating a new method (NIOSH 1607, 1984) and is considering its adoption as a standard method. Several of these methods have been validated by USAEHA at low ETO concentrations (less than 1 ppm) both in the laboratory and during field comparison sampling. Such methods are useful for determining breathing zone ETO concentrations and for general area sampling.

b. The Qazi-Ketcham charcoal tube method is a proposed America Society for Testing and Materials standard method for determining ETO in air. This method uses a large charcoal tube (700 mg in the front section and 390 mg in the back section) to adsorb ETO from air, which is pumped through the tube at a known flow rate. The mass of ETO collected is determined by gas chromatography. When divided by the total sample volume, the TWA concentration of ETO in air during the sampling period can be determined.

(1) Some disadvantages of this method include:

(a) A low sampling rate (20 mL/min) is required to prevent sample breakthrough.

(b) High relative humidity levels compete for adsorption sites. High relative humidity is common in the CMS environment.

(c) The tubes must be refrigerated below 41 °F (5 °C) from the time of sampling to the time of analysis to avoid sample loss. The only practical way to ensure this temperature is to ship on dry ice.

(d) Sampling pumps must be pre and post calibrated to accurately determine volumetric flow rates.

(e) Other organic compounds can possibly interfere with the analysis.

(2) Some advantages of the Qazi-Ketcham method include:

(a) It is a relatively inexpensive method.

(b) It can be used for STEL sampling with minimal adjustment. All that is necessary is an increased flow rate.

(c) This method has been validated by USAEHA. However, it is no longer used by USAEHA since the method described in paragraph d below is easier to use and analyze.

c. The OSHA method number 30 for ETO (Salt Lake City method) is also a charcoal tube method. Details of the sampling and analysis procedures are contained in 29 CFR 1910.1047, Appendix D. This method can provide valid data; however it is complex and is subject to the above disadvantages except interference from other organic compounds. This method has not been evaluated by USAEHA.

d. A monitoring tube developed by USAEHA is now commercially available from Supelco, Inc. The ORBO-78 ethylene oxide tube simultaneously adsorbs and derivatizes ETO. The derivative is analyzed in the laboratory with a gas chromatograph. Tubes can be used for short or long term sampling, are unaffected by high (90 percent) relative humidity, and do not require refrigeration. This method has been validated by USAEHA, and has undergone extensive field testing. This method is recommended by USAEHA.

e. Common to all of these sampling methods is the requirement for calibrated sampling pumps. Low flow rates are preferred (30 mL/min) in order to minimize the number of sampling tubes. For each sampling session, lab blanks are subjected to the same handling as samples, except that no air is drawn through the tubes. The ends of the tubes are broken off, and immediately covered with plastic caps. These blanks are shipped for laboratory analysis along with the sample tubes. Refer to USAEHA TG-141, Industrial Hygiene Sampling Instructions.

C-3. PASSIVE (DIFFUSIONAL) SAMPLING METHODS.

a. Passive sampling devices are available for determining ETO concentrations. The 3M Model 3550 and 3551 ETO monitors contain charcoal impregnated with a derivating reagent which reacts with ETO and retains it on the charcoal. With the Dupont Pro-Tek ETO badge, a liquid absorbent is used to collect and entrain ETO in solution via a chemical reaction. Gas chromatography is used to analyze the 3M monitor, and a wet chemical method is used for the Pro-Tek badge. The USAEHA performs analysis of the 3M Model 3551 ETO monitors; it is not set up to analyze the DuPont badges.

b. Passive diffusional samplers offer possible advantages over conventional active sampling methods. They require no pump or tubing, are lightweight, and are mechanically more reliable than active methods. Since they interfere very little with normal movement, they are likely to meet with good worker acceptance. These devices are convenient and easy to use; however, the cost is significantly greater than a charcoal tube. The higher cost is somewhat offset by a savings in time, labor, and equipment cost and maintenance, since no pump or calibration of the passive sampler is required. Additionally, the supervisor of the employees to be monitored can perform the simple tasks necessary to obtain accurate measurements with passive samplers.

c. The 3M passive ETO sampler has been validated by USAEHA and is the method of choice for breathing zone samples. Detailed operating procedures are in section II of this appendix. The Model 3550 includes analysis by 3M; the 3551 does not. Requests for analysis of 3551 monitors must be made directly to the Organic and Environmental Chemistry Division, USAEHA, AUTOVON 584-2208.

d. Passive samplers are best suited for determining TWA breathing zone exposures. Since passive samplers rely on diffusion to collect ETO, a minimum face velocity (air flow across the opening of the sampler) is required to prevent stagnant air conditions and sampler starvation and to ensure a valid sample. Passive samplers should not be used for general area sampling. Section III, to this appendix contains a brief discussion on the theory behind diffusional samplers.

C-4. MIRAN INFRARED SPECTROPHOTOMETERS.

a. The MIRAN IA is a single-beam spectrophotometer equipped with a variable wavelength filter that has a scanning spectral range from 2.5 to 14.5 μm. The cell pathlength is adjustable from 0.75 to 20.25 meters. For monitoring ETO, the 3.3 μm wavelength with a pathlength of 20.25 m and a slit width of 2 mm should be used since a fluorocarbon absorbance band overlaps at 11.8 μm. According to the manufacturer, the sensitivity of the instrument at 3.3 μm is 0.2 ppm and the response time is 15 seconds in continuous operation. The instrument has a self-contained air pump and an air hose for continuous sampling capability. The MIRAN 103 uses filters of a specific wavelength; it should be equipped with a 3.3 μm filter for use with ETO. To continuously record changing concentrations, a strip chart recorder or data logger should be used with either instrument. The purpose of using a MIRAN as a continuous monitor is to characterize the cyclic release of ETO and to measure the peak short term exposures of employees. It may also be used to detect leaks.

b. If available, two MIRANs can be used as fixed area monitors to simultaneously monitoring two separate but related points such as the area in front of the sterilizer and a point immediately above the sterilizer door. This will provide some information about how much of the ETO emitted from the sterilizer escapes into the operator's breathing zone.

c. The MIRAN can also be used as a mobile monitor, sampling a particular point for 15 to 20 minutes to obtain an estimate of the magnitude and transient nature of the ETO concentration at that point. Various points in the workroom can be monitored in this manner to include workstations, areas under supply-air outlets and ventilation inlets, and areas of suspected high concentration.

d. The MIRAN can measure the worker's short term exposure profile. The sampling hose can be positioned in the worker's breathing zone during brief periods involving potentially high exposure. The operator can be monitored in this manner while opening the sterilizer door and transferring items to the aerator. The employees who change the tanks and perform maintenance operations can also be monitored for the duration of these procedures.

e. Caution should be used when interpreting results from areas with high relative humidity (greater than 80 percent) since water vapor also absorbs at the 3.3 μm wavelength. This will result in an indicated ETO concentration that is higher than the actual concentration.

Section II. Directions for Use of 3M Passive Diffusional Monitors for ETO

C-5. OVERVIEW OF SAMPLING PROCEDURE.

a. Scope. This procedure covers the method of collecting and analyzing samples using the 3M Ethylene Oxide Monitor to determine the amount of ETO present in air. These monitors are used to measure the concentration of ETO to which personnel are exposed in their workplace during the total time period the monitor is worn. The monitors will be worn for an entire work shift, normally 8 hours. During the workshift, selected individuals will also be sampled for a 20-minute period to determine STEL concentrations during the transfer of sterilized items to the aerator. Monitors will not be used more than one time.

b. Summary of Method. The ETO gas is adsorbed on chemically treated activated charcoal where it is converted to 2-Bromoethanol. The 2-Bromoethanol is desorbed with an appropriate solvent and quantified using a gas chromatograph equipped with an electron capture detector.

c. Sampling.

(1) Only the primary users of ETO sterilizers should be sampled (e.g., all CMS workers and workers in other areas where ETO sterilizers are used). Sampling should be conducted on two consecutive workdays to account for variability in exposure. The individual who transfers the items from the sterilizer to the aerator should also be sampled for a 20-minute period starting at the time he or she opens the sterilizer door at the end of the sterilization cycle. The area should be vacated for 10 minutes; upon return, transfer the items to the aerator.

(2) The monitor is removed from the package and the exposure start time is recorded on the back of the monitor. While personnel sampling is being performed, the monitor must be attached near the breathing zone. The shirt or scrub suit collar is an acceptable location for the monitor. At the conclusion of the sampling period, the monitor is removed from the collar, and the retaining ring and the membrane are removed and discarded. The elutriation cap (plastic cover) is then immediately snapped on ending the monitor exposure and the stop time is recorded on the back of the monitor. The following information must be recorded for each sample on the monitor bag.

Monitor number
Date exposed
Employee I.D. (initials and last 4 of SSN)
Temperature and relative humidity (RH) of the monitored environment if greater than 85°F or 70% RH
Any comments or unusual circumstances (e.g., STEL sample)

(3) Detailed sampling instructions are enclosed with each box of monitors.

C-6. DISCUSSION.

a. Interferences. A single contaminant is rarely found by itself in a given industrial atmosphere. Because of the chemical process involved in the collection and the analytical procedure, this method is considered to be specific. Compounds chemically similar to ETO (i.e., containing the epoxy ring) will react. However, their products are normally easy to resolve chromatographically because of increasing boiling points and molecular weights.

b. Sample Stability. Historically, storage of ETO samples has proven to be most difficult even with refrigeration. This is principally due to the high vapor pressure exhibited by the compound. With the ETO monitor, the storage problem has virtually been eliminated.

Section III. Theory of Operation of Passive Diffusional Samplers

C-7. Passive diffusional sampling devices are gaining wide acceptance among industrial hygienists in settings where exposures of personnel to potentially hazardous vapors must be measured. In contrast to an active sampler in which the air sample is brought into contact with a collector by a pump, the passive sampler collects the substance of interest from its immediate surroundings by virtue of the natural diffusion or permeation of the substance into the sampler and from there onto or into a trapping medium. The amount thus collected is related to the integrated dose or TWA concentration of the substance in the sampled environment. Relative to active sampling systems, passive samplers are generally simple in construction and require no power for operation. They are small, light in weight, and easy to use.

C-8. Diffusional samplers rely on the movement of the contaminant molecules across a concentration gradient, which for steady-state conditions, can be defined by Fick's First Law of Diffusion:

$$W = - DA \frac{dc}{dx} \qquad (1)$$

where: W = mass transfer rate, ng/sec
D = diffusion coefficient, cm^2/sec
A = cross-sectional area of diffusion path, cm^2

$\frac{dc}{dx}$ = the instantaneous rate of change in concentration over diffusion path $(ng/cm^3)cm^{-1}$

a. Considering the change in concentration $(C_1 - C_o)$ over the total diffusion path length $(X_1 - X_o = -L)$, equation (1) becomes:

$$W = D \frac{A}{L} (C_1 - C_o) \qquad (2)$$

where: L = length of the diffusion (static) path, cm
C_1 = ambient concentration of contaminant, ng/cm^3
C_o = concentration of contaminant at collecting surface face, ng/cm^3

b. If an effective collection medium is employed, the contaminant concentration at the surface of the collector (C_0) can be assumed to be zero, and multiplying both sides of equation (2) by time, yields:

$$M = D \frac{A}{L} (C_1)\, t \qquad (3)$$

where: M = total mass transferred, ng
t = time that the monitor is exposed to the contaminated air, seconds

C-9. Note that the units of the product of D and A divided by L are cm^3/sec, which are the same units associated with active sampling air moving devices such as personal sampling pumps.

C-10. By rearranging equation (3) as shown in equation (4), it becomes apparent that five factors affect the measurement of the ambient air concentration of a substance (C_1).

$$C_1 = \frac{ML}{DAt} \qquad (4)$$

Factors L and A are physical parameters associated with the construction of the sampler; factor M is provided by measuring the total mass of contaminant collected by the sampler. Factor t is the duration the sampler was exposed to the contaminated atmosphere, and the final factor, D, is an individual property of each gas or vapor. The diffusion coefficient is directly proportional to the absolute temperature (T) of the vapor raised to the three-halves power and inversely proportional to the atmospheric pressure (P).

$$D \propto \frac{T^{3/2}}{P} \qquad (5)$$

C-11. The most obvious sources of error for passive diffusional samplers are apparent from equation (4). These are: determinations of the mass of contaminant collected and the time of exposure of the monitor to the contaminated atmosphere, accurate knowledge of the length and cross-sectional area of the monitor, and the diffusion coefficient of the contaminant.

a. The problems associated with accurate determinations of the mass of the contaminant collected are similar to those involved with other collection devices such as charcoal or silica gel tubes. Using known amounts or concentrations of contaminants to determine collection and/or desorption efficiencies is as critical a step for passive diffusional samplers as it is for other methods of collection. Saturation of the sorbent and the accuracy of analytical techniques are also part of the total error associated with the measurement. Another common concern in all types of environmental measurements is the potential for either positive or negative interferences from other contaminants in the sampled air.

b. Three factors have the greatest effect on the variability of the diffusion coefficient. Two have already been identified, temperature and pressure. The third factor is the velocity of the air external to the monitors. Changes in temperature and pressure affect D as indicated in equation (5), however, at the same time they also affect the concentration of the contaminant (concentration is inversely proportional to the temperature and directly proportional to the pressure). As a result, the total mass (M) collected by the monitor is only slightly affected by temperature ($M \propto T^{1/2}$) and is independent of the pressure. A temperature change from 77 to 86 °F (25 to 30 °C), if uncorrected, will introduce a measurement error of less than 1 percent, while a change from 41 to 95 °F (5 to 35 °C), if uncorrected, would introduce an error of about 5 percent.

c. The diffusion coefficient of a molecular species in air is a function of certain intrinsic properties of the species and may be measured experimentally or may be calculated from any variety of empirical and semiempirical equations. In a study of nine such equations, it was concluded that the Hirschfelder, Bird, and Spotz equation agreed most closely with experimental values of D for high molecular weight compounds, whereas the Chen and Othmer equation or the Wilke and Lee equation provided more accurate values for low molecular weight vapors. This study suggests that the determination of D may be a significant source of error in passive diffusional sampling.

d. The final source of error to consider is the velocity of the air external to the monitor, often referred to as the face velocity. With zero or low face velocities, the length (L) of the diffusion pathway is effectively extended, and there is a decrease in the measured ambient concentration. The critical minimum velocity beyond which the sampler performance quickly becomes virtually insensitive to velocity is about 15 ft/min. High face velocities may also affect the concentration gradient. Commercially available diffusion devices rely on either a large ratio of diffusion path length to diffusion tube diameter or a windscreen to limit errors from this condition. The windscreen prevents the inner diffusion gradient from being disrupted by air movement in the vicinity of the inlet. As long as the pores in the windscreen are greater than about 1 μm in diameter, the wind-screen's effects upon the diffusion characteristics of the sampler can be determined from equation (1), and frequently are negligible.

e. Although numerous factors may affect the final calculation of concentration, only face velocity and the determination of the diffusion coefficient are unique sources of error for passive diffusional samplers. If face velocities are sufficient to prevent starvation of the sorbent, and if diffusion coefficients have been accurately calculated or experimentally determined, passive diffusional samplers should give results comparable to those obtained with active sampling methods.

C-12. For further information, consult the 1982 American Industrial Hygiene Association Journal article by Rose and Perkins.

Appendix D
Ventilation Guidelines

D-1. FLOOR DRAIN VENTILATION.

a. Many sterilizers operate on water-sealed-pumps. When a final vacuum is pulled, large quantities of water are mixed with the evacuated chamber gas and are discharged into an open floor drain, often near the sterilizer. Additional ventilation at the floor drain is often not needed when the drain pipes have sealed connections to a remote sewer line emptying outside the room or building and away from people. When the floor drain is located inside the building, particularly near the sterilizer, the precautions in paragraph b below are necessary.

b. There should be a sealed, trapped drain pipe running from the floor drain to the sewer line so that no gases vent into the room. Local exhaust ventilation should be located above the floor drain to remove any ETO that did not stay in solution with the drain water during the final vacuums. Specially designed "capture boxes" are marketed as a retrofit option by several sterilizer manufacturers.

D-2. ETHYLENE OXIDE CYLINDER VENTILATION. To reduce exposure in cases when the hose is not properly connected to the cylinders, LEV is needed. A separate ventilation hood and branch duct of approximately 4 inches in diameter should be located directly above the cylinders.

D-3. STERILIZER VENTILATION. A slot or canopy-type exhaust hood should move 100 cubic feet of air per minute per square foot of door area to provide effective control. Local exhaust ventilation located above the door is the best design since heated air generated by the sterilizer rises.

Appendix E
Selected Bibliography

Industrial Ventilation, A Manual of Recommended Practices. American Conference of Governmental Industrial Hygienists, current edition.

Ethylene Oxide Use in Hospitals, A Manual for Health Care Personnel. Copies may be obtained from American Hospital Association, 840 North Lake Shore Drive, Chicago, Illinois 60611.

Health Industry Manufacturers Association Report 80-4, The Safe Use of Ethylene Oxide, December 1980. Copies may be obtained from the Health Industry Manufacturers Association, 1030 15th Street, NW, Washington, DC 20005.

Rose, V. E. and Perkins, J. L. Passive Dosimetry - State of the Art Review. AIHAJ 43:605-621(1982).

Glossary

Section I
Abbreviations

ACGIH
American Conference of Governmental Industrial Hygienists

CFR
Code of Federal Regulations

CMS
central materiel supply

ETO
ethylene oxide

FR
Federal Register

LEV
local exhaust ventilation

NIOSH
National Institute for Occupational Safety and Health

OSHA
Occupational Safety and Health Administration

OTSG
Office of The Surgeon General

PEL
permissible exposure limit

ppm
parts per million

RH
relative humidity

SCBA
self-contained breathing apparatus

SOP
standing operating procedure

SSN
social security number

STEL
short-term exposure limit

TWA
time-weighted average

USAEHA
US Army Environmental Hygiene Agency

Section II
Terms

Action level. A concentration of airborne ETO of 0.5 ppm calculated as an eight (8)-hour time-weighted average.

Emergency. Any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that is likely to or does result in an unexpected significant release of ETO.

Employee exposure. Exposure to airborne ETO which would occur if the employee were not using respiratory protective equipment.

Ethylene oxide (ETO). The three-membered ring organi compound with chemical formula C_2H_4O.

END

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